UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA
CASE NO: _____

MDL No. 2391
IN RE: BIOMET M2A MAGNUM HIP IMPLANT PRODUCT LIABILITY LITIGATION

THOMAS L. HIPPE

and

LINDA WILLIAMS PLAINTIFFS

v.

BIOMET ORTHOPEDICS, LLC
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

and

BIOMET, INC.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

and

BIOMET MANUFACTURING CORP.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

and

BIOMET US RECONSTRUCTION, LLC
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587 DEFENDANTS

COMPLAINT

1. This is a product liability case involving a defective hip implant system. Plaintiff Thomas L. Hippe, had Biomet M2a Magnum Metal-on-Metal Hip Systems (or its predecessor the M2a-38) ("M2a Magnum Hip System")[1] implanted in his left hip. The M2a Magnum Hip System suffers from defects that cause excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve, which in turn causes the hip implant to fail and the surrounding tissue and bone to die. As a result of these defects, Mr. Hippe's M2a Magnum Hip Systems had an unreasonably high risk of failing in his body, causing toxic levels of cobalt and chromium, tissue and bone destruction, and the need for Mr. Hippe to undergo a complicated and risky surgery to remove and replace the defective implant. Additionally, Plaintiff Linda Williams (Hippe's Wife) brings a claim for loss of consortium.

PARTIES

2. Plaintiffs Thomas L. Hippe ("Hippe") and Linda Williams ("Williams") are citizens and residents of Newport News, Virginia.

3. All of the named Defendants are organized and existing under the laws of the state of Indiana and are all citizens of that state with their primary place of business in Warsaw, Indiana. Biomet, Inc. is the sole member of both Biomet Orthopedics, LLC and Biomet US Reconstruction, LLC. As previously stated, Biomet, Inc. and Biomet Manufacturing Corp. are Indiana corporations and are citizens of Indiana with their primary place of business in Warsaw, Indiana. Defendants designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip system that is the subject of this lawsuit.

[1] Reference to the M2a Magnum hereinafter shall also include the M2a-38.

4. Defendants do not maintain a principal local office in Virginia, but can be served at 56 East Bell Drive, P.O. Box 587, Warsaw, Indiana 46581-0587.

5. Pursuant to the Case Management Order filed Feb. 15, 2013, in the above-referenced Multi-District Litigation No. 2391, Defendants agree to accept service by mail.

6. At all times mentioned, each Defendant was the representative, agent, employee, joint venturer, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, promotion, and sale of the M2a Magnum Hip System. Therefore, it would be inequitable for any Defendant to escape liability for an obligation incurred as much for that Defendant's benefit as for the other.

7. All Defendants are collectively referred to herein as "Biomet."

JURISDICTION AND VENUE

8. This is a civil action of which this has original jurisdiction under 28 U.S.C. section 1332 because it is between citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interest.

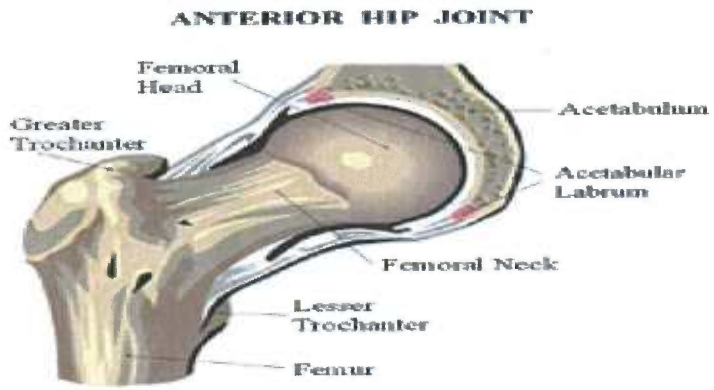
9. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a)(1) because one or more of the Defendants reside in this district and all Defendants reside in Indiana and are subject to personal jurisdiction in this district.

FACTUAL BACKGROUND

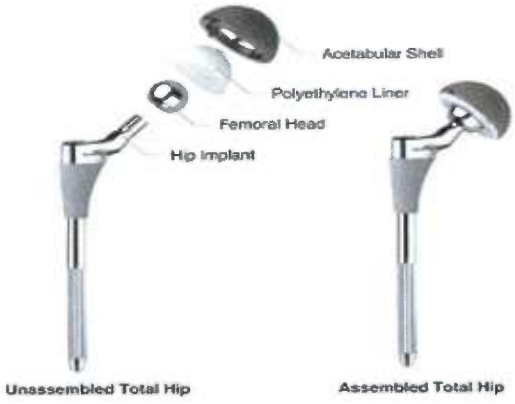
A. The M2a Magnum Hip System Is Defective And Was Not Adequately Tested

10. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the

acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.



11. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem (labeled as "hip implant" in the diagram to the left), (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.



12. While most hip replacements use a polyethylene ***plastic*** acetabular liner, Biomet's M2a Magnum Hip System has a critical difference: it is a monoblock system which does not have an acetabular liner. Instead, the M2a Magnum Hip System forces metal to rub against metal with the full weight and pressure of the human body. Because of Biomet's defective

design for the M2a Magnum Hip System, hundreds of patients—including Mr. Hippe—have been forced to undergo surgeries to replace the failed hip implants.

13. The M2a Magnum Hip System suffers from a design or manufacturing defect that cause excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

14. The design of the M2a Magnum Hip System was not sufficiently tested by Biomet, and it was never approved by the FDA as being safe or effective for the products' intended purpose.

15. On numerous occasions, Biomet met with orthopedic surgeons in cities throughout the United States to promote the M2a Magnum Hip Implant. At some or all of these meetings, a representative or representatives of Biomet was present. During these meeting, Biomet assured the orthopedic surgeons that the M2a Magnum Hip System was safe, was the best product on the market, had an excellent track record and a low and acceptable failure rate. Biomet continued to "defend" the M2a Magnum Hip Implant even after they became aware of numerous and serious complications with the M2a Magnum Hip System. Biomet did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

B. Biomet Sold the M2a Magnum Hip Implant To Mr. Hippe After It Knew It Was Defective, That It Had Injured Others, And That It Would Injure Him.

16. It was not long after Biomet launched the M2a Magnum Hip System that reports of failures began flooding into Biomet. For example, in August 2004, Biomet received a

complaint that a patient had to undergo a surgery to remove and replace an M2a Magnum Hip System because it had become loose after only 3 years. Biomet closed its investigation of this complaint.

17. Biomet would go on to receive hundreds of similar complaints reporting that the M2a Magnum Hip System had failed and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. To date, more than 350 reports of adverse events associated with the M2a Magnum Hip System have been filed with the FDA.

18. By the time Biomet sold the M2a Magnum Hip System to Mr. Hippe, numerous reports had been filed with the FDA reporting an adverse event associated with the M2a Magnum Hip System. Consequently, Biomet was fully aware that the M2a Magnum Hip System was defective and that dozens of patients already had been injured by that defect. Based on this information, Biomet should have recalled the M2a Magnum Hip System before it was sold to Mr. Hippe. At minimum, Biomet should have stopped selling the defective implant when it became aware that it had catastrophically failed in several patients.

19. Despite its knowledge that the M2a Magnum Hip System had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, Biomet continues to sell the defective M2a Magnum Hip System. In so doing, Biomet actively concealed the known defect from doctors and patients—including Mr. Hippe and his doctor—and misrepresented that that the M2a Magnum Hip System was a safe and effective medical device.

20. As numerous failures of the M2a Magnum Hip Implant were reported to Biomet, it continued to actively promote, market and defend the defective products. For example,

Biomet published marketing brochures touting the safety and durability of metal-on-metal implants and specifically, the M2a Magnum Hip System. These brochures were given to doctors around the world to encourage them to use the M2a Magnum Hip System.

21. Despite its knowledge that the M2a Magnum Hip System was defective, Biomet also made several false representations about specific design elements of the M2a Magnum Hip System that they claimed made it superior to other more safe hip implants on the market. For example, Biomet said:

- "The M2a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates *in vivo*."
- Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

22. Biomet's reason to conceal the defect in its M2a Magnum Hip System is clear. Hip implant sales are critically important to Biomet, and the M2a Magnum is one of its most profitable products. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet look appealing to investors, and they ultimately were purchased by a private equity firm in 2007 for $10 billion. Biomet was faced with a critical defect in one of its most profitable hip implant systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, Biomet decided that it would continue to promote, market, and sell the M2a Magnum Hip System despite the fact that it knew the product was defective. To this day,

Biomet continue to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Mr. Hippe's M2a Magnum Hip System Was Defective.

23. On or about Apgil 17, 2008, Hippe underwent a left hip replacement surgery in Columbia, South Carolina, during which a Biomet metal-on-metal M2a Magnum prosthesis was implanted in his body. By this time, numerous reports of adverse events associated with the M2a Magnum had been filed with the FDA and Biomet knew that the product was defective. But Biomet refused to disclose that information to Mr. Hippe, his physicians, or the public. Instead, Biomet misrepresented to Mr. Hippe and his orthopedic surgeon that the M2a Magnum Hip System was safe and effective. In reliance on these representations, Mr. Hippe's orthopedic surgeon made the decision to use the M2a Magnum Hip System. If it were not for the misrepresentations made by Biomet, Mr. Hippe's orthopedic surgeon would not have used the M2a Magnum Hip System in Mr. Hippe's hip replacement surgery.

24. As a result of the defective design, manufacture and composition of the M2a Magnum Hip System, and its accompanying warnings and instructions (or lack thereof), Mr. Hippe's hip implant has caused him severe pain and he was forced to undergo costly and painful revision surgery on the left hip on March 20, 2013.

25. Having to go through revision surgery has subjected Mr. Hippe to much greater risks of future complications than he had before the revision surgeries. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and his colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who

underwent a original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al.* Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

26. As a direct and proximate result of the failure of his defective M2a Magnum Hip System and Biomet's wrongful conduct, Mr. Hippe sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Mr. Hippe has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed $75,000 jurisdictional minimum of this court.

COUNT I
(Strict Product Liability)

27. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here.

34. Biomet designed, manufactured, promoted, distributed, marketed, and sold the M2a Magnum Hip System.

28. At all times material hereto, the M2a Magnum Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was expected to reach, and did reach, prescribing physicians and consumers, including Mr. Hippe and Mr. Hippe's physician, without substantial change in the condition in which it was sold.

29. At all times material hereto, the M2a Magnum Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was in a defective and

unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

(a) When placed in the stream of commerce, the M2a Magnum Hip System contained manufacturing defects, subjecting Mr. Hippe and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

(b) When placed in the stream of commerce, the M2a Magnum Hip System contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting Mr. Hippe and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

(c) The M2a Magnum Hip System was insufficiently tested; and

(d) The M2a Magnum Hip System was not accompanied by adequate instructions and/or warnings to fully inform Mr. Hippe or his physicians of the full nature or extent of the risks associated with its use.

30. Biomet knew or should have known of the dangers associated with the use of the M2a Magnum Hip System, as well as the defective nature of the M2a Magnum Hip System. Despite this knowledge, Biomet continued to manufacture, sell, distribute, promote and supply the M2a Magnum Hip System so as to maximize sales and profits at the expense of the public health and safety. Biomet's conduct was done in conscious disregard of the foreseeable harm caused by the M2a Magnum Hip System and in conscious disregard for the rights and safety of consumers such as Mr. Hippe.

31. Mr. Hippe and his surgeon used the M2a Magnum Hip System as directed for its intended purpose.

32. At all times herein mentioned, the M2a Magnum Hip System was defective, and Biomet knew that it was to be used by the user without inspection for defects therein. Moreover, at the time of the use of the subject products, neither Mr. Hippe nor his physician knew or had reason to know of the existence of the aforementioned defects. Neither Mr. Hippe nor his physicians could have discovered the defects in the M2a Magnum Hip System through the exercise of reasonable care.

33. The M2a Magnum Hip System had not been materially altered or modified prior to its implantation in Mr. Hippe.

34. As a direct and proximate result of the failure of the defective M2a Magnum Hip System, Mr. Hippe suffered the injuries and damages as described herein.

COUNT II
(Negligence)

35. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here.

36. At all times herein mentioned Biomet had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the M2a Magnum Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.

37. Biomet maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the M2a Magnum Hip System.

38. Biomet, maliciously, recklessly and/or negligently made misrepresentations about the safety and effectiveness of the M2a Magnum Hip System to Plaintiff and his orthopedic surgeon. In reliance on these misrepresentations, Plaintiff's orthopedic surgeon decided to use the M2a Magnum Hip Implant in Plaintiff's surgery. If it was not for the misrepresentations by Biomet, Plaintiff's orthopedic surgeon would not have used the M2a Magnum Hip System in Plaintiff's surgery.

39. Biomet maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Mr. Hippe and his physicians as to the risks of the M2a Magnum Hip System.

40. Biomet maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the M2a Magnum Hip System when they knew or should have known of said risks.

41. Biomet's conduct was done in conscious disregard of the foreseeable harm caused by the M2a Magnum Hip System and in conscious disregard for the rights and safety of consumers such as Mr. Hippe.

42. As a result of Biomet's wrongful conduct, Mr. Hippe suffered injuries and damages as alleged herein.

COUNT III
(Breach of Implied Warranties)

43. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here.

44. Prior to the time that the M2a Magnum Hip System was used by Mr. Hippe, Biomet impliedly warranted to Mr. Hippe and his physicians that the M2a Magnum Hip System was of merchantable quality and safe and fit for the use for which it was intended.

45. Mr. Hippe and his physician were and are unskilled in the research, design and manufacture of the M2a Magnum Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Biomet in using the M2a Magnum Hip System.

46. The M2a Magnum Hip System was neither safe for its intended use nor of merchantable quality, as warranted by Biomet, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

47. Biomet, by selling, delivering and/or distributing the defective M2a Magnum Hip System to Mr. Hippe, breached the implied warranty of merchantability and fitness and caused Mr. Hippe to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

48. As a result of the aforementioned breach of implied warranties by Biomet, Mr. Hippe suffered injuries and damages as alleged herein.

COUNT IV
(Breach of Express Warranty)

49. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here.

50. At all times herein mentioned, Biomet expressly warranted to Mr. Hippe and his physicians, by and through statements made by Biomet or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned M2a Magnum Hip System was safe, effective, fit and proper for its intended use.

51. In utilizing the aforementioned M2a Magnum Hip System, Mr. Hippe and his physician relied on the skill, judgment, representations and foregoing express warranties of Biomet.

52. Said warranties and representations were false in that the aforementioned M2a Magnum Hip System was not safe and was unfit for the uses for which it was intended.

53. As a result of the foregoing breach of express warranties by Biomet, Mr. Hippe suffered injuries and damages as alleged herein.

COUNT V
(CONSUMER PROTECTION ACT)

54. Plaintiff realleges and reincorporates each of the allegations above as if set forth fully here.

55. Defendants are liable to Mr. Hippe pursuant to the Indiana's Defective Consumer Protection Act and/or the Virginia Consumer Protection Act. Defendants were in the business of manufacturing and marketing the implant. Defendants and/or their agents designed, formulated, manufactured, assembled, prepared for sale, distributed, and/or sold the implant which was in a defective condition unreasonably dangerous when applied to its intended use in the usual and customary manner.

56. Privity existed between Mr. Hippe and Defendants.

57. Mr. Hippe, while using the product in the usual and customary manner as it was intended to be used, suffered substantial injuries as a proximate result of Defendants placing the product on the market, which was unreasonably dangerous and defective at the time it was placed on the market by Defendants.

58. The implant, at the time of Mr. Hippe's injuries and damages, was in substantially the same condition as it was at the time the implant was marketed by the Defendants.

59. As a direct and proximate result of Defendants' conduct, Mr. Hippe was injured and are entitled to recover damages for their bodily injuries, lost wages, physical and mental pain, past and future medical expenses, past and future pain and suffering, increased risk of

future harm and permanent injury. Additionally, Mr. Hippe is entitled to recover punitive damages.

COUNT VI
(LOSS OF CONSORTIUM)

58. Plaintiffs reallege and reincorporate each of the allegations above as if set forth fully here.

59. Because of Defendants' conduct as described above, and the corresponding injuries sustained by their spouses, Williams is entitled to recover for the loss of services, assistance, aid, society, companionship and conjugal relationship between her and her husband Hippe.

PRAYER FOR RELIEF

THEREFORE, Plaintiffs demand judgment for the following:

1. Past and future lost wages, medical, permanency and incidental expenses, according to proof;
2. Past and future general damages for pain and suffering, according to proof;
3. Punitive and exemplary damages in an amount to be determined at trial;
4. Prejudgment and post judgment interest;
5. Costs to bring this action; and
6. Such other and further relief as the court may deem just and proper.

Respectfully submitted,

Counsel for Plaintiffs

/s/ H. David Gibson
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